

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>SAT)**

Acquisition Plan Action ID: 36C261-20-AP-1206/ 662-20-1-045-0032

1. **Contracting Activity:** Department of Veterans Affairs, Veterans Health Administration, Regional Procurement Office West, Network Contracting Office 21 on behalf of VA Palo Alto Health Care System.

2. **Nature and/or Description of the Action Being Processed:**

The purpose is to establish a purchase order for lease of FDA approved glucose meter system for SFVA. Approval is requested for a sole source purchase order with Nova Biomedical, the manufacturer of the glucose meter. There is no authorized distributor.

The period of performance shall consist of a base year and (4) year option. The estimated period of performance is as follows:

Base Year	\$ 55,757.19
Option Year 1	\$ 55,757.19
Option Year 2	\$ 55,757.19
Option Year 3	\$ 55,757.19
Option Year 4	\$ 55,757.19
Total	\$ 278,785.95

Estimated total price is \$278,785.95 for base + 4 option year

3. **Description of Supplies/Services Required to Meet the Agency's Needs:**

Yearly lease includes the following deliverables, equipments, warranty and licenses:

StatStrip Glucose Strips (1,800 test strips/case)-Cases
Includes the following:
StatStrip Clucose Meter - QTY 55 EA
Single Docking Station - QTY 22 EA
Dual Docking Station - QTY 16 EA
Statstrip Carrying Case - QTY 55 EA
Single Wall Mount - QTY 10 EA
Dual Wall Mount - QTY 2 EA
StatSrip Extended Meter Warranty to 5 years
StatStrip Batterues (PK4 of 4) - 2 PK
Full connectivity using Alere RALS system, including support, installation, and site licenses for all provided. glucometers.
Items to be ordered as needed (estimates):
Control Solution 1, StatStrip 1 btl/pkg
Control Solution 3, StatStrip 1 btl/pkg
Statstrip Linearity kit (5 levels, 1 of each btl)

4. Statutory Authority Permitting Other than Full and Open Competition:

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- () (2) Unusual and Compelling Urgency per FAR 6.302-2;
- () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- () (4) International Agreement per FAR 6.302-4
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7;

FAR13.5 Simplified Procedures for Certain Commercial Items: The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

There is only one vendor that meets the requirement for an FDA cleared system for all patient settings at this medical center, including those who are considered critically ill and in the intensive care unit. Nova Biomedical recently received FDA clearance that will meet our needs. There is no other vendor with this approval.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**

Notice of Intent 36C26120Q0339 was posted in BetaSAM on February 26, 2020. There were no responses from any interested and/or capable vendors.

7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:**

The pricing quoted will be determined fair and reasonable in accordance with (IAW) FAR 13.106-3(a)(2)(ii) prices found reasonable on previous purchases.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**

VIP search was not conducted as this is sole source to the manufacturer. This item is not available from 3rd parties reseller.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None

11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:**

Agency may remove barrier when additional FDA approved equipment is available in the market for commercial use.

12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

Kristopher Taylor
Lab Manager
Laboratory Medicine Service

Date

13. **Approvals in accordance with the [VHAPM Part 806.3 OFOC SOP](#):**

a. **Contracting Officer or Designee's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Mandy Thompson
Branch Chief, Supply I
NCO 21

Date:

- b. **One Level Above the Contracting Officer (Required over SAT but not exceeding \$700K:** I certify the justification meets requirements for other than full and open competition.

Brett Vegeto
Chief, Division II
NCO 21

Date: